

10/511108

#2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DT04 Rec'd PCT/PTO 08 OCT 2004

In re application of:

Ruediger Ridder, *et al.*

Appl. No. Not Yet Assigned

Filed: October 8, 2004

For: METHOD FOR DISCRIMINATION OF  
MATAPLASIAS FROM NEOPLASTIC OR  
PRENEOPLASTIC LESIONS

Attorney Docket Number:

05033.0006PCUS00

### Information Disclosure Statement

Mail Stop PCT  
Attention: DO/EO/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120.

1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed;
  - ☐ a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
  - b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - ☒ c. Before the mailing date of a first Office Action on the merits;
  - ☐ d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

- ☐ 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or
  - ☐ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).

- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i), and
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

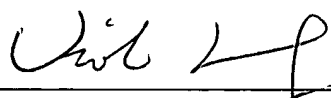
Attorney Docket No. 05033.0006PCUS00

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05033.0006.PCUS00.

Respectfully submitted,

Date: October 8, 2004

  
\_\_\_\_\_  
Viola T. Kung (Reg. No. 41131)

**HOWREY SIMON ARNOLD & WHITE, LLP**  
2941 Fairview Park Drive,  
Box 7  
Falls Church, VA 22042  
Tel: (650) 463-8181  
Fax: (650) 463-8400

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

**Complete if Known**

Application Number

10/511108

Filing Date

October 8, 2004

First Named Inventor

**RIDDER, Ruediger**

## Art Unit

Examiner Name

05033.0006.PCUS00
-------------------

Sheet

1

9

1

**A**

Attorney Docket Number

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>2</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
		WO 02 08764 A	01-31-2002	DOORBAR, JOHN		
		EP 1 217 377 A	06-26-2002	BAYER AG		
		WO 00 01845 A	01-13-2000	VON KNEBEL D.	whole document	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number

**10/511108**

Filing Date

**October 8, 2004**

First Named Inventor

RIDDER, Ruediger

Art Unit

Examiner Name

Sheet

1

of

1

Attorney Docket Number

05033.0006.PCUS00

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1 ✓	SANO T ET AL: "Expression status of p16...", American Journal of Pathology, Philadelphia, PA, US, vol. 153, no.6, 1998-12, pages 1741-1748	
	2 ✓	RIETHDORF S ET AL: "Analysis of p16/MTS1...", Virchows Archiv, vol. 439, no. 3, 2001-09, page 338	
	3 ✓	MILDE-LANGOSCH Karin et al: "Expression of cyclin-dependent kinase inhibitors...", Virchows Archiv, vol. 439, no.1, 2001-07, pages 55-61	
	4 ✓	KONNO R ET AL: "Detection of human papillomavirus DNA...", Tohoku Journal of Experimental Medicine, Japan, vol. 168, no. 3, 1992-11, pages 491-497	
	5	CHOO K B ET AL: "Integration of human papillomavirus type 16...", Virology, US, vol. 161, no. 1, 1987-11, pages 259-261. <i>Abstract</i>	
	6 ✓	NINDL I ET AL: "Human papillomavirus distribution in cervical tissues...", Int. Journal of Gynecological Pathology, New York, NY, US, vol. 16, no. 3, 1997, pages 197-204	
	7 ✓	KLAES RUEDIGER ET AL: "Overexpression of p16INK4a as a specific marker...", International Journal of Cancer, vol 92, no. 2, 2001, pages 276-284	
	8 ✓	WIEST Tina et al: "Involvement of intact HPV16 E6/E7 gene expression...", Oncogene, vol. 21, no. 10, 2002-02, pages 1510-1517. <i>Abstract</i>	
	9 ✓	SDEK Patima et al: "Influence of HPV16 on expression of RB...", Chinese Journal of Stomatology, China, vol. 37, no.2, 2002-03, pages 84-86. <i>Abstract</i>	

Examiner  
Signature

Date

Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.